



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

Mr. Frank J. Alvino
President
MGA Development Corporation
900 Pompton Avenue
Cedar Grove, New Jersey 07009

MAR - 6 1998

2584 98 MAR 17 P1:41

Dear Mr. Alvino:

This is in response to your letter of November 24, 1997 to the Food and Drug Administration (FDA) pursuant to section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the act). Your submission states that MGA Development Corporation is making the following claims for the product "Citrol:"

"Citrol can help you get other [sic] those immediate moments when you want to smoke"

"Use Citrol to reduce your desire to smoke in any smoke-free environment"

"With its tart, citrus taste, Citrol can help you get over those immediate moments when you want to smoke"

"Citrol -- a pocket-sized oral spray -- can help smokers cope with those immediate moments when they want to smoke, but can't"

Section 403(r)(6) of the act makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statements that you are making for this product suggests that it is intended to treat, prevent, cure, or mitigate a disease, namely addiction to nicotine (i.e., smoking). These claims do not meet the requirements of section 403(r)(6) of the act. These claims suggest that this product is intended for use a drug within the meaning of section 201(g)(1)(B) of the act, and that it is subject to regulation under the drug provisions of the act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

Please contact us if we may be of further assistance.

Sincerely,

James T. Tanner, Ph.D.
Acting Director
Division of Programs and Enforcement Policy
Office of Special Nutritionals
Center for Food Safety
and Applied Nutrition

975-0163

LET 109

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Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300

FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of Enforcement, HFC-200

FDA, New Jersey District Office, Office of Compliance, HFR-MA340

cc:

HFA-224 (w/incoming)

HFA-305 (docket 97S-0163)

HFS-22 (CCO, JGordon)

HFS-456 (File)

HFS-450 (file, r/f)

HFD-310 (BWilliams)

HFD-314 (Aronson)

HFS-600 (Reynolds)

HFS-605 (Bowers)

GCF-1 (Nickerson, Dorsey)

r/d:HFS-456:RMoore:12/12/97

init:GCF-1:DDorsey:1/27/98

f/t:HFS-456:rjm:1/27/98:docname:56063.adv:disc25

Office of Special Nutritionals

November 24, 1997

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Dietary Ingredient that is the Subject of the Statement

Citric Acid in an oral spray.

Sincerely,

A handwritten signature in dark ink, appearing to read "Frank J. Alvino", with a horizontal line drawn underneath it.

Frank J. Alvino
President